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Patent  
Attorney Docket No. 017753-183

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

Liliane Goetsch et al.

Application No.: 10/735,916

Filing Date: December 16, 2003

Title: NOVEL ANTI-IGF-IR ANTIBODIES AND USES THEREOF

Group Art Unit: 1644

Examiner: PHOUNG N HUYNH

Confirmation No.: 5622

AMENDMENT/REPLY TRANSMITTAL LETTER

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Enclosed is a reply for the above-identified patent application.

- ☐ A Petition for Extension of Time is also enclosed.
- ☐ Terminal Disclaimer(s) and the ☐ \$65.00 (2814) ☐ \$130.00 (1814) fee per Disclaimer due under 37 C.F.R. § 1.20(d) are also enclosed.
- ☒ Also enclosed is/are a Return Receipt Postcard

- ☐ Small entity status is hereby claimed.
- ☐ Applicant(s) requests continued examination under 37 C.F.R. § 1.114 and enclose the ☐ \$395.00 (2801) ☐ \$790.00 (1801) fee due under 37 C.F.R. § 1.17(e).
- ☐ Applicant(s) requests that any previously unentered after final amendments not be entered. Continued examination is requested based on the enclosed documents identified above.
- ☐ Applicant(s) previously submitted \_\_\_\_\_  
\_\_\_\_\_ on \_\_\_\_\_  
for which continued examination is requested.
- ☐ Applicant(s) requests suspension of action by the Office until at least \_\_\_\_\_, which does not exceed three months from the filing of this RCE, in accordance with 37 C.F.R. § 1.103(c). The required fee under 37 C.F.R. § 1.17(i) is enclosed.
- ☐ A Request for Entry and Consideration of Submission under 37 C.F.R. § 1.129(a) (1809/2809) is also enclosed.

- ☒ No additional claim fee is required.
- ☐ An additional claim fee is required, and is calculated as shown below.

AMENDED CLAIMS					
	No. of Claims	Highest No. of Claims Previously Paid For	Extra Claims	Rate	Additional Fee
Total Claims	54	MINUS 54 =	0	x \$50.00 (1202) =	\$ 0.00
Independent Claims	1	MINUS 3 =	0	x \$200.00 (1201) =	\$ 0.00
If Amendment adds multiple dependent claims, add \$360.00 (1203)					
Total Claim Amendment Fee					\$ 0.00
<input type="checkbox"/> Small Entity Status claimed - subtract 50% of Total Claim Amendment Fee					\$ 0.00
<b>TOTAL ADDITIONAL CLAIM FEE DUE FOR THIS AMENDMENT</b>					<b>\$ 0.00</b>

- ☐ A check in the amount of \_\_\_\_\_ is enclosed for the fee due.
- ☐ Charge \_\_\_\_\_ to Deposit Account No. 02-4800.
- ☐ Charge \_\_\_\_\_ to credit card. Form PTO-2038 is attached.

The Director is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17, 1.20(d) and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in duplicate.

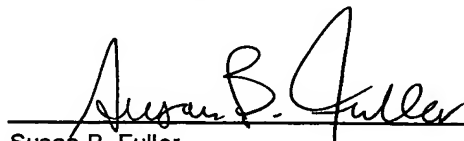
Respectfully submitted,

BUCHANAN INGERSOLL LLP

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Suite 300  
San Diego, CA 92130-2090  
(858) 509-7300

Date: November 30, 2005

By

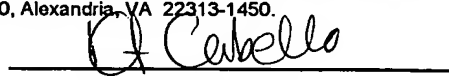


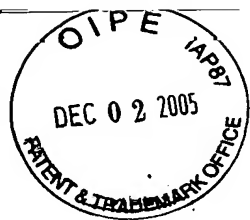
Susan B. Fuller

Registration No. 51,979

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Date of Deposit: November 30, 2005

  
Kim A. Cabello  
Typed Name:



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For: NOVEL ANTI-IGS-IR ANTIBODIES )  
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Group Art Unit: 1644

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By: \_\_\_\_\_

*KA Cabello*  
Kim A. Cabello

**RESPONSE TO RESTRICTION REQUIREMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This Response is being submitted in response to the Restriction Requirement of November 2, 2005. Accordingly, this response is timely filed.

### **ELECTION OF GROUP I**

In the Official Communication mailed on November 2, 2005, the Examiner sets forth a restriction requirement among seven groups of the claims:

Group I, claims 1-17, 22-30, and 43-54, drawn to an isolated antibody, or one of its functional fragments that binds human insulin-like growth factor T receptor and inhibits the natural attachment of its ligands IGF1 and/or IGF2 and/or capable of specific the tyrosine kinase activity of said receptor, a hybridoma producing said antibody, a process of producing said antibody, a composition comprising said antibody or functional fragments thereof and a pharmaceutically acceptable carrier, a method for the preparation of a medicament using said antibody and a kit comprising said antibody;

Group II, claims 18-20, drawn to an isolated nucleic acid encoding an isolated antibody;

Group III, claim 21, drawn to a transgenic animal;

Group IV, claims 31-35, and 43-44, drawn to a composition comprising an isolated antibody, or one of its functional fragments that binds human insulin-like growth factor T receptor, and a second compound wherein the second compound is an anti-EGFR antibodies;

Group V, claims 36-39, and 43-44, drawn to a composition comprising an isolated antibody, or one of its functional fragments that binds human insulin-like growth factor T receptor, and a second compound wherein the second compound is a cytotoxic/cytostatic agent;

Group VI, claims 36, 40, and 43-44, drawn to a composition comprising an isolated antibody, or one of its functional fragments that binds human insulin-like growth factor T receptor, and a second compound wherein the second compound is an inhibitor of tyrosine kinase activity; and

Group VII, claims 41-44, drawn to a composition comprising an isolated antibody, or one of its functional fragments that binds human insulin-like growth factor T receptor, and a second compound wherein the second compound is another antibody that directed against the extracellular domain of the HER2/neu receptor.

Applicants herewith elect Group I, claims 1-17, 22-30, and 43-54, drawn to an isolated antibody, *with traverse*.

The Office has restricted the claims into seven groups. According to the general policy as articulated in the MPEP, “since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334, it is *improper* for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984).” (MPEP 803.02, emphasis added). Specifically, in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978), the court articulated the general proposition that:

[A]n applicant has a right to have *each* claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not affect the right of the applicant eventually to have each of the claims examined in the form he considers to best define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on its merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification.

Id. at 331.

Applicants respectfully assert that the presently claimed subject matter clearly exhibits unity of invention. With regard to a common utility, as well as a substantial structural feature, the compounds of the present claims associate with antibodies that bind

human insulin-like growth factor T receptor and inhibit the natural attachment of its ligands IGF1 and/or IGF2 and/or capable of specific the tyrosine kinase activity of said receptor (*e.g.*, claims 1-17, 22-30, and 43-54, in Group I) and compositions comprising such antibodies (*e.g.*, claims 31-44, in Groups IV-VII). The Examiner has indicated that claim 30 is a linking claim and will be examined along with Groups IV-VII if any one of said Groups is elected (page 3, final paragraph). As Group I includes claim 30, Applicants respectfully submit that joinder of Groups I and IV-VII is proper, that the compounds of the present claims clearly evidence unity of invention, and there would be no undue burden in searching.

Further, Applicants submit that any nominal burden placed upon the Examiner to search accordingly to determine the art relevant to Applicants' overall invention is significantly outweighed by the public's interest in not having to obtain and study many separate patents in order to have available all of the issued patent claims covering Applicants' invention. The alternative is to proceed with the filing of multiple applications, each consisting of generally the same disclosure, and each being subjected to essentially the same search, perhaps by different Examiners on different occasions. This process would place an unnecessary burden on both the Patent and Trademark Office and on the Applicants.

Regardless of whether the alleged seven inventions are independent or distinct, Applicants respectfully assert that the Examiner need not have restricted the application. MPEP § 803 requires that "[i]f the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to independent or distinct inventions." Therefore, it is not mandatory to make a restriction requirement in all situations where it would be deemed proper. As noted above, the compounds and compositions recited in the claims all have common utility, and so there would not be an undue burden for the Office to search all Groups.

Reconsideration and withdrawal of the restriction requirement are requested.

Applicants have no intention of abandoning any non-elected subject matter and expressly reserve the right to file one or more continuation and/or divisional applications directed to the non-elected subject matter.

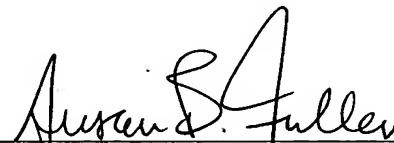
Applicants earnestly solicit favorable consideration of the above response and early passage to issue the present application. The Examiner is invited to contact the undersigned at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted,

BUCHANAN INGERSOLL L.L.P.

Date: November 30, 2005

By: \_\_\_\_\_



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